

**REMARKS**

The Office Action dated April 16, 2008 (hereinafter, "Office Action") has been reviewed and the Examiner's comments considered. Claims 1-5, 7-8, and 10-36 are pending in this application. Claims 1, 7, 8, and 15 are amended herein. Applicants submit that no new matter or issues have been introduced.

**Claim Rejections – 35 U.S.C. § 112**

Claims 7, 8, and 15 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has amended claims 7, 8, and 15 herein to change the dependency from canceled claim 6 to pending independent claim 1. Accordingly, Applicant respectfully requests withdrawal of this objection.

**Claim Rejections – 35 U.S.C. § 103**

Claims 1-5, 10-14, and 16-28 stand rejected under 35 USC § 103(a) as being unpatentable over USPN 5,695,499 to Helgerson (hereinafter, "Helgerson") in view of USPN 6,702,802 to Hancock (hereinafter, "Hancock") and USPN 5,690,643 to Wijay (hereinafter, "Wijay"). Claims 29-32 and 34-46 stand rejected under 35 USC § 103(a) as being unpatentable over Helgerson in view of Hancock and Wijay, as applied to claim 24, and further in view of US 2002/0016597 to Dwyer (hereinafter, "Dwyer"). Claim 33 stands rejected under 35 USC § 103(a) as being unpatentable over Helgerson in view of Hancock and Wijay, as applied to claim 24, and further in view of USPN 5,458,615 to Klemm (hereinafter, "Klemm"). Applicant respectfully traverses these rejections.

**Claims 1-5, 10-14, and 16-23**

The Office Action alleges that Helgerson discloses an inner catheter including a wire coil 32. The Office Action admits that although Helgerson "acknowledges that the wire coil 32 has closely spaced coils (col. 4, lines 14-17) or may have spaces that exist between some of the coils (col. 4, lines 35-38), it is not expressly disclosed to have a closed-coil structure at an intermediate

region of the wire coil and an open-coil structure at proximal and distal regions of the wire coil.” Office Action, p. 3. The Office Action further admits that Helgerson does not disclose the wire coil being disposed around an inner tube.

The Office Action finds the features admittedly missing from the primary reference to Helgerson in secondary references to Hancock and Wijay, and alleges that substituting these features into the Helgerson device would have been obvious to one of ordinary skill in the art. In particular, the Office Action alleges that Hancock teaches a wire coil with the claimed structure and that Wijay teaches an open coil surrounding an inner tube. Applicant submits that a *prima facie* case of obviousness is not established at least because: (1) not all of the claimed elements are shown or described by the cited combinations, and (2) neither of the secondary references are properly combined with the primary reference, each combination clearly the result of impermissible hindsight analysis with the benefit of Applicant’s own disclosure.

With respect to the Helgerson/Hancock combination, the Office Action alleges that Hancock in FIG. 16 “teaches a catheter with a wire coil having a closed-coil structure at an intermediate region 279 and an open-coil structure at proximal and distal 277 regions.” Office Action, p. 4. However, this allegation is not supported by Hancock. Hancock describes a balloon catheter including an inner tubular member 46 with a proximal inner member 145 and distal inner member 148, “the sections decreasing in stiffness in the distal direction.” Hancock, col. 10, ll. 13-16. Regarding FIG. 16, Hancock states that “an inner member 46’ comprises, *at least in its distal section* 148’, a tubular member 271 with an imbedded coil 274 for providing a gradual change in stiffness profile of the catheter *near and at the stent region*.” Hancock, col. 14, ll. 53-57, emphasis added. Hancock further states that the coil may have a variable pitch that is open at a first point *near the balloon proximal end*, as the coil moves *distally away from the proximal edge of the stent*, and as the coil moves *distally away from the distal edge of the stent*. Hancock, col. 14, l. 59 to col. 15, l. 2, emphasis added.

In other words, rather than showing the claimed wire structure including a proximal, intermediate, and distal region, the intermediate region having a closed-coil structure, Hancock

shows and describes only a distal region, which has an open/closed/open/closed/open structure, meaning that the intermediate portion of the distal region is open. Thus, even assuming *arguendo* that this distal region of the Hancock inner tubular member 46 could be interpreted as having a wire coil with a proximal, intermediate and distal region, there still is no support for the claimed intermediate region having a closed-coil structure.

Further, the Helgerson wire coil includes coils that are closely spaced “similar to a solid spring” and have a preferably rectangular cross-section to present an inner surface that permits a guidewire to easily slide through. Helgerson, col. 4, ll. 11-21. Thus, even though Helgerson states that the wire could be wound such that spaces exist between some or all of the coils, one skilled in the art would not look to modify the Helgerson coil to include an open coil configuration, such as that shown in Hancock. More specifically, while small spaces between coils (e.g., less than the guidewire diameter) may not affect the smooth travel of a guidewire, large spaces such as the open configuration shown in Hancock (i.e., greater than the guidewire diameter), would change the principle of operation of the Helgerson device as a guidewire could no longer slide through the inner tube as intended (e.g., the guidewire would be pushed through the open regions). Therefore, contrary to the allegations in the Office Action, one of ordinary skill in the art would not substitute the Hancock coil for the Helgerson coil. Accordingly, Applicant submits that the Helgerson/Hancock combination is improper.

With respect to the Helgerson/Wijay combination of disposing an additional inner tube within the Helgerson inner tube, the Office Action is silent regarding any articulated reasoning with some rationale underpinning to support the conclusion of obviousness. While the Office Action alleges that it would have been obvious to substitute the open-coil structure of Wijay for the Helgerson coil (which allegation Applicant has shown above to be unsupported and without merit), there isn’t an identified reason why a person of ordinary skill in the art would have been prompted to add a further inner tube to the Helgerson device. Accordingly, in the absence of any analysis, much less an explicit one, Applicant submits that the combination of Helgerson/Wijay is insufficient to support a *prima facie* case of obviousness. See *KSR Int’l Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_\_ (2007), 82 USPQ2d 1385, 1395 (2007).

In view of the above, Applicant submits that a *prima facie* case is not established by the cited combinations such that independent claim 1, and claims 2-5, 10-14, and 16-23 depending therefrom, are patentable. Accordingly, Applicant requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 103.

As should be clear from the remarks above, the amendment to claim 1 herein, support for which can be found in the originally filed application at, for example, pp. 15-17, is not made for any reason related to patentability.

#### Claims 24-28

Claim 24 recites, *inter alia*, “an annular gap between the inner polymeric tube and wire coil.” In addition to the remarks above, Applicant submits that no reasoning is supplied in the Office Action supporting the obviousness of the feature of an annular gap as claimed. Therefore, Applicant submits that a *prima facie* case is not established by the cited combinations such that independent claim 24, and claims 25-28 depending therefrom, are patentable. Accordingly, Applicant requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 103.

#### Claims 29-32 and 34-36

Applicant notes that the combination used in the Office Action to reject claims 29-32 and 34-36 relies on a combination of Wijay and Dwyer, which combination was appealed and *overturned* in view of a decision to withdraw the rejection and re-open prosecution mailed in a Notice of Panel Decision from Pre-Appeal Brief Review dated November 12, 2007. Accordingly, at least for this reason, claims 29-32 and 34-36 are patentable over the cited combination. Moreover, Applicant submits that, in view of the above, each of claims 29-32 and 34-36 depends from patentable independent claim 24 and is therefore patentable. Thus, Applicant respectfully requests favorable reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a).

Claim 33

Without conceding to any of the allegations in the Office Action or the propriety of the asserted combination, Applicant submits that, in view of the above, claim 33 depends from patentable independent claim 24 and is therefore patentable. Accordingly, Applicant respectfully requests favorable reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

**Conclusion**

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

It is noted that the remarks herein do not constitute, nor are they intended to be, an exhaustive enumeration of the distinctions between the cited references and the claimed invention. Rather, the distinctions identified and discussed herein are presented solely by way of example. Consistent with the foregoing, the discussion herein should not be construed to prejudice or foreclose future consideration by Applicant of additional or alternative distinctions between the claims of the present application and the references cited by the Examiner and/or the merits of additional or alternative arguments.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 50-2191 referencing docket no. 1016710009P. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

Electronic signature: /Todd W. Wight/

Todd W. Wight

Registration No.: 45,218

RUTAN & TUCKER LLP

611 Anton Boulevard

Costa Mesa, California 92626

(714) 641-3460